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EXAMINER	
ROYDS, LESLIE A	

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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,784	DULIN, JACQUES M.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006 and 12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 September 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are presented for examination.

Applicant's petition to make the instant application special pursuant to 37 C.F.R. 1.102(c)(1) and MPEP §708.02(IV) has been previously acknowledged by the Examiner.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and request filed October 12, 2006 has been received and entered into the present application. Accordingly, prosecution has been reopened. The Information Disclosure Statement filed September 18, 2006 with the after-final amendment(s), which was previously denied consideration due to a failure to pay the fee required under 37 C.F.R. 1.17(p), has been considered by the Examiner. Please see the attached, completed copy of form PTO/SB/08A (two pages total).

Claims 1-15 are pending and are under examination. Claim 5 remains withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 16-20 are cancelled and claims 1-2, 5 and 10-13 are amended.

Applicant's arguments, filed October 12, 2006, have been fully considered but they are not persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Applicant's Traversal of the Requirement for Restriction/Election

Applicant again traverses the restriction requirement of November 9, 2005, which was made final in the Office Action dated June 20, 2006.

Applicant states that the restriction requirement made a scientifically unsupported statement as the basis for restricting claim 5 between benzoic acid and boric acid and relies upon the Office Action where it asserts that, "The claimed product can be employed in a materially different process, such as insertion of the cotton roll impregnated with the antimicrobial agent, benzoic acid, directly into a wound as a plug to promote antimicrobial action and healing."

However, Applicant appears to be confusing the requirement for restriction between patentably distinct inventions, i.e., in the present case, the claimed delivery system and the claimed method for oral hygiene, with the requirement for election of species. The assertion that the claimed product can be employed in a materially different process as stated *supra* was the basis for requiring restriction between the claimed delivery system and the claimed method. It was not relied upon to "restrict" benzoic acid from boric acid. This was done as an election of species of a single topical oral medication. Therefore, Applicant's remarks regarding Dr. Stillman's discussion of wound infection have been duly noted, but are not persuasive in establishing error in the propriety of the restriction requirement.

Applicant further asserts that the Examiner is incorrect in stating that the claimed delivery system could be used in an allegedly materially different process, such as the use of a cotton roll impregnated with benzoic acid as a wound plug. First, it is noted that, in accordance with the MPEP at §806.05(h)[R-3], "The burden is on the Examiner to provide an example, but the example need not be documented." Therefore, Applicant's assertions that this is an unsubstantiated example are not persuasive because the Examiner is not required by the MPEP to document the example provided. Additionally, Applicant's allegation that such a proposed use could not be accomplished rests upon the argument that if one were to insert a cotton roll impregnated with benzoic acid mouthwash into a wound, then contact dermatitis would result. This is an inherently flawed argument because: (1) the example proposed the use of benzoic acid itself, which is a known antibacterial agent, not benzoic acid mouthwash, and (2) insertion of a wound plug is common practice in the medical arts to promote tissue granulation in deep wound healing to avoid

abscess formation resulting from superficial skin healing prior to actual healing of the subcutaneous tissue.

Applicant's remarks regarding the "mischaracterization of the invention" based upon its intended use have been noted, but are also not persuasive. Applicant is reminded that the presently claimed delivery system is, according to the statutory categories of invention that can be claimed in U.S. patent practice, a "composition" of matter insofar as it is composed of a cotton roll and a topical oral medication. Applicant is not prohibited from claiming such an invention, however, it is noted that whatever process that Applicant intends to use the composition of matter for is irrelevant to the composition itself because it does not structurally or materially change the physical components of the composition itself. The Office is not arbitrarily choosing to ignore Applicant's claim limitations. Each and every limitation has been fully considered to determine whether such limitations provide a physical or structural limitation to the overall generic structure of the claimed delivery platform. Where no such physical or structural limitation is made, the limitation is not patentably limiting to the composition. Please see, for example, MPEP §2111.02[R-3].

Regarding Applicant's present allegation(s) that the election of the invention and species pursuant to the restriction requirement of November 9, 2005 was made **with traverse**, where it was understood to be made **without traverse** during the telephone conversation of November 9, 2005, Applicant's attention is directed to MPEP §708.02(VIII), which outlines the special examination procedure for accelerated examination of applications afforded special status. In particular, the MPEP states:

"A new application (one which has not received any examination by the examiner) may be granted special status provided that applicant (and this term includes applicant's attorney or agent) complies with each of the following items: ...

(B) Presents all claims directed to a single invention, or if the Office determines that all the claims presented are not obviously directed to a single invention, will make an election without traverse as a prerequisite to the grant of special status.

The election may be made by applicant at the time of filing the petition for special status. Should applicant fail to include an election with the original papers or petition and the Office determines that a

requirement should be made, the established telephone restriction practice will be followed.

If otherwise proper, examination on the merits will proceed on claims drawn to the elected invention.

If applicant refuses to make an election without traverse, the application will not be further examined at that time. The petition will be denied on the ground that the claims are not directed to a single invention, and the application will await action in its regular turn.

Divisional applications directed to the nonelected inventions will not automatically be given special status based on papers filed with the petition in the parent application. Each such application must meet on its own all requirements for the new special status...".

Claims 1-4 and 6-15 remain under examination. Claim 5 remains properly withdrawn. The restriction requirement has been reconsidered, but remains proper. **Finality is maintained.**

Claim Rejections - 35 USC § 112, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claims 1 and 10 and the claims dependent therefrom are directed to a medication delivery platform and a portable consumer package having a plurality of individual delivery platforms containing a sterile disposable cotton roll carrying a topical oral medication treatment composition for effecting the treatment of adverse periodontal conditions "at dosage amounts substantially lower than conventional mouthwash."

In particular, Applicant has failed to provide adequate written support to now claim effecting the treatment objective (i.e., treating the periodontal condition) using any dosage amount substantially lower than conventional mouthwash.

Regarding Applicant's newly added limitation to effect treatment of periodontal conditions (i.e., bad breath and gingivitis) "at dosage amounts substantially lower than conventional mouthwash", Applicant fails to direct the Examiner to the specific portion of the specification that provides adequate written support to now claim effecting the treatment of periodontal conditions at any "dosage amounts substantially lower than conventional mouthwash."

However, the Examiner has carefully considered the specification as originally filed for written support for this newly claimed limitation. Relevant disclosure was found at page 13, lines 1-4, which states:

"The suggested dosage of popular liquid mouthwashes is 20 mL so that 1 Litre provides 50 applications and 1.5 L provides 75 applications. In contrast, the inventive medicated roll system as a dosage unit need employ only from .75-3 ml, a total of 4-12 per application, some 40-80% less than popular liquid mouthwashes, but with equal or greater effectiveness."

However, such disclosure of, specifically, a dosage amount of 0.75-3 ml, which is an amount less than popular liquid mouthwash, is not adequate written support to broaden the claim(s) to now read upon the use of "any" dosage amount that is substantially lower than conventional mouthwash. The specific disclosure of a particular range of dosage amounts that is effective for achieving the intended therapeutic objective as disclosed in the specification does not provide adequate written support to now claim an entire genus of dosage amounts that are substantially lower than conventional mouthwash and still capable of effecting the claimed therapeutic purpose. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is, therefore, clear that Applicant was not in

possession of the concept of using any or all dosage amounts that are substantially lower than conventional mouthwashes but still capable of achieving the disclosed therapeutic objective(s) at the time of the invention, with the exception of those dosage amounts explicitly stated in the specification at page 13.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of the use of any dosage amount substantially lower than conventional mouthwash to effect treatment of periodontal conditions.

Accordingly, for these reasons, claims 1-4 and 6-15 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended part (b) of present independent claim 1 to now read, "a topical oral medication treatment composition effective to treat said adverse periodontal conditions carrier by and releasably absorbed in said roll in an extended-release, single use dosage amount that is therapeutically effective to treat said adverse periodontal conditions", and has amended part (ii) of present independent claim 10 to now read, "a topical oral medication treatment composition in fluid or gel form in an amount

effective to treat said adverse periodontal conditions carried by and releasably absorbed in said roll in an extended-release, single use dosage amount that is therapeutically effective to treat said adverse periodontal conditions."

In particular, it is unclear exactly what Applicant intends by the phrase "releasably absorbed". Merriam-Webster (Online, 2006) defines release as, "to see free from restraint, confinement, or servitude; to let go", and absorb as, "to take in and make part of an existent whole." In other words, "release" and "absorb" are, effectively, antonyms of one another and, therefore, the meaning intended by the phrase "releasably absorbed" is ambiguous and renders the scope of the subject matter for which Applicant is seeking protection unclear. Accordingly, the skilled artisan would not have been reasonably apprised of the meaning of this phrase and, in turn, the metes and bounds of the claimed subject matter.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of

Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 1 and 10 recite the broad limitation "ordinary life activities", and then goes on to state, "including speaking", a narrower statement of the limitation. Such a recitation renders the claim indefinite because it is unclear as to whether Applicant intends to claim that the delivery system does not interfere with or restrict ordinary life activities in general or if Applicant intends to claim that the delivery system does not interfere with or restrict speaking only. As a result, the boundaries of the claim cannot be readily identified.

In addition, it is unclear exactly what activities Applicant intends by the phrase "ordinary life activities". Given that the present specification only provides an exemplary teaching of those activities considered "ordinary" and, thus, within the scope of the claims, the skilled artisan would not have been reasonably apprised of the scope of the term "ordinary life activities" and what activities were either included or excluded from the claim(s). In addition, it is noted that the term "ordinary" is a subjective term and leaves the limitation open to subjective interpretation as to whether one would consider a particular activity "ordinary" or not.

For these reasons, claims 1-4 and 6-15 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et

al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997).

Regarding independent claim 1, the claim recites a medication delivery system consisting essentially of the physical components of a sterile disposable cotton roll substrate and a topical oral medication treatment composition carried by said cotton roll in an extended release, single use dosage amount that is therapeutically effective to treat said adverse periodontal conditions. Applicant's intended use of the composition, i.e., for the treatment of adverse periodontal conditions or the insertion of the cotton roll into the buccal vestibule etc., are limitations that have been fully considered by the Examiner, but fail to impart any material, physical or structural property to the overall generic structure of the claimed delivery platform. As previously stated *supra*, where no such physical or structural limitation is made, limitations of intended use(s) or function(s) of a combination of matter (i.e., in the present instance, a cotton roll carrying a topical oral medication) are not patentably limiting to the combination. Please see, for example, MPEP §2111.02[R-3].

Masci et al. teaches improved antimicrobial compositions for controlling bacteria and other microorganisms, wherein the composition contains a decamethylene 1,10-bis-4-aminoquinaldinium salt (col.1, lines 11-15) and a cetyl pyridinium salt (col.2, lines 55-57), and further wherein the composition may be aqueous, as in the case of a solution (col.8, lines 20-22) and, additionally, wherein the active composition is incorporated into or applied to dental articles, such as cotton rolls (col.8, lines 12-16).

The claimed subject matter differs from the teachings of Masci et al. by employing benzoic acid as the antimicrobial agent carried by the cotton roll and using a cotton roll of 3/16"-7/16" in diameter and 1"-2" in length (see present claim 7).

However, Vermeer provides teachings that benzoic acid was an antibacterial agent commonly used in oral hygiene compositions, which was known to have activity against a wide variety of microorganisms at levels below those known to be harmful (col.35, line 66-col.36, line 30; see, in particular, col.36, line 20).

One having ordinary skill in the art would have found it *prima facie* obvious to combine the teachings of Masci et al. with Vermeer et al. to apply the antimicrobial agent benzoic acid to the cotton roll of Masci et al. because Vermeer teaches that benzoic acid was not only amenable for use in dental or oral hygiene products, but also that it was known to provide potent broad-spectrum antibacterial activity at concentrations much lower than those concentrations that would result in toxicity to the host. In other words, the use of benzoic acid as the antibacterial agent applied to the cotton roll of Masci et al. would have naturally commended itself, and would have been *prima facie* obvious, to the skilled artisan because benzoic acid would have provided the same or substantially similar level of antibacterial activity to the decamethylene and cetylpyridinium salts of Masci et al. with the additional benefit of achieving such a level of efficacy at much lower concentrations than would pose serious toxicicological risk to the subject.

Regarding the specific dimensions of the cotton roll, the determination of the optimum diameter or length of the cotton roll to be employed would have been a matter well within the purview of the skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the size of the subject's mouth, the medicament impregnated into the cotton roll and the dose of the medicament to be administered. Moreover, Applicant is reminded that where the only difference between the prior art and the claimed is a recitation of the relative dimensions of the claimed composition, and wherein such a difference in the dimensions does not result in an appreciable difference in function of the composition, then the presently claimed dimensions do not patentably distinguish the presently claimed composition from that of the cited prior art. Please see MPEP §2144.04(IV).

Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Wiesel (U.S. Patent No. 6,287,120; 2001).

Masci et al. and Vermeer et al. as applied above.

The claimed subject matter differs from the combined teachings of Masci et al. and Vermeer et al. by applying the oral medication as a gel (see present claim 2).

However, Wiesel provides teachings of the benefits and increased efficacy of employing topical solutions for use on the teeth or in the oral cavity in gel formulation, rather than liquid formulations. Wiesel teaches, "Topically applied antiseptics, such as mouthwashes, are easily washed from the site of infection by salivation and routine mastication. Thus, a need exists for an oral composition which is effective in combating growth of infection causing bacteria which is capable of adhering to the site of the infection and being retained in the oral cavity." (col.2, line 64-col.3, line 7)

One having ordinary skill in the art would have found it *prima facie* obvious to combine the teachings of Masci et al. and Vermeer with Wiesel to apply the antimicrobial agent in the form of a gel because Wiesel teaches that gel formulations of topical oral or dental antiseptics are less likely to wash away from the site of infection by the saliva or during mastication, thus, increasing the antiseptic action of the agent. In other words, the use of a gel formulation of the oral medication would have naturally commended itself, and would have been *prima facie* obvious, to the skilled artisan because the gel formulation would have provided enhanced therapeutic activity over a liquid or aqueous formulation because the gel was more likely to adhere to the site of infection and to, thus, be retained in the oral cavity, thereby prolonging the therapeutic antiseptic action of the oral medication.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Julius (U.S. Patent No. 4,071,955; 1978) or Speaker et al. (U.S. Patent No. 4,917,892; 1990).

Masci et al. and Vermeer et al. as applied above.

The claimed subject matter differs from the combined teachings of Masci et al. and Vermeer et al. by employing a cotton roll that includes a core of absorbent fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material (see present claim 8) or using a braided cotton roll with a diameter of 5/16" and a length of about 1.5" (see present claim 9).

However, Julius provides teachings of an absorbent sponge-like material laminated with at least one layer of woven or non-woven fabric-like material, such as cotton gauze or cotton batting, which is capable of absorbing more than a conventional sponge composition and does not leave lint behind in the oral cavity (see abstract, col.2, lines 7-10 and 32-34). Additionally, Speaker et al. provides teachings that braided cord was commonly used in dental applications to provide highly sustained localized topical drug delivery and to serve as a drug reservoir (col.1, lines 55-61).

One having ordinary skill in the art would have found it *prima facie* obvious to combine the teachings of Masci et al. and Vermeer et al. with Julius or Speaker because Julius teaches the benefits of laminating an absorbent material with at least one layer of a woven or non-woven fabric-like material (i.e., cotton gauze or cotton batting) to enhance the absorbent properties of the material and to avoid leaving lint behind in the oral cavity and Speaker teaches the braided cord was amenable for dental applications, particularly for its ability to provide highly sustained localized topical drug delivery and also to serve as a drug reservoir by which to effect the sustained release. Thus, the use of either a layer of laminated woven or non-woven cotton material over the cotton roll of Masci et al. or the use of a braided cotton cord would have naturally commended themselves, and would have been *prima facie* obvious, to the skilled artisan motivated by the desire to enhance the absorbency of the cotton to retain more of the antiseptic and/or to sustain localized topical delivery of the antiseptic over a longer period of time, thereby enhancing the therapeutic effect of the antiseptic agent.

Regarding the specific dimensions of the cotton roll, the determination of the optimum diameter or length of the cotton roll to be employed would have been a matter well within the purview of the

skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the size of the subject's mouth, the medicament impregnated into the cotton roll and the dose of the medicament to be administered. Moreover, Applicant is reminded that where the only difference between the prior art and the claimed is a recitation of the relative dimensions of the claimed composition, and wherein such a difference in the dimensions does not result in an appreciable difference in function of the composition, then the presently claimed dimensions do not patentably distinguish the presently claimed composition from that of the cited prior art. Please see MPEP §2144.04(IV).

Claims 1-4, 6-7, 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Copelan et al. (U.S. Patent No. 5,133,971; 1992).

Masci et al. and Vermeer et al. as applied above.

The claimed subject matter differs from the combined teachings of Masci et al. and Vermeer et al. by a portable consumer package containing a plurality of cotton rolls (see present claims 10 and 13), which is a sealed, water-impervious pouch and sized to fit in a shirt pocket and further contains a manually openable and/or reclosable seal member (see present claims 10-11), such as a tear-off strip with a zip-type closure (see present claims 12), and further wherein a plurality of the pouches are packaged in a box (see present claim 15).

However, Copelan provides teachings of a simple, edge sealed packet of protective material, such as coated or uncoated paper that is adhesively or mechanically bonded at its edges to form a rectangular pouch, wherein the packet may be made of foil or moisture impervious sheet plastic material (col.4, lines 28-37), used to carry cotton fiber mats impregnated with cleansing agents (col.4, lines 63-66).

One having ordinary skill in the art would have found it *prima facie* obvious to combine the

teachings of Masci et al. and Vermeer et al. with Copelan because the skilled artisan would have been motivated by a desire to facilitate distribution and portability of a plurality of antiseptic carrying cotton rolls (to allow for multiple applications). Additionally, one of ordinary skill in the art would have been motivated to use the packaging described according to Copelan because the water-impervious packet would have retained the efficacy of the cotton rolls by protecting them from contacting water, which would leach out and/or dilute the impregnated antiseptic agent prior to use.

Furthermore, the skilled artisan would have been motivated to modify the package of Copelan to be resealable, for preserving the sterility of a plurality of cotton rolls contained within the package for use at a later time, as well as pocket-sized, such that the rolls could be easily and discretely transported on one's person. In addition, the overall packaging of such packets into a box would have been *prima facie* obvious to the skilled artisan motivated by a need to ship, transport or move a volume of cotton rolls in order to facilitate distribution of the rolls.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Copelan et al. (U.S. Patent No. 5,133,971; 1992) and in further view of Julius (U.S. Patent No. 4,071,955; 1978) or Speaker et al. (U.S. Patent No. 4,917,892; 1990).

Masci et al., Vermeer et al. and Copelan et al. as applied above.

The claimed subject matter differs from the teachings of Masci et al., Vermeer et al. and Copelan et al. by using a pouch with a width of about 1.75"-2.25" and a length of about 2"-2.5"; a cotton roll with a diameter ranging from about 3/16"-7/16" and a length of about 1"-2"; and also by employing a cotton roll that includes a core of absorbent fibers and a sheath selected from a mesh braiding and a highly permeable woven or non-woven sheet material (see present claim 14).

However, Julius provides teachings of an absorbent sponge-like material laminated with at least

one layer of woven or non-woven fabric-like material, such as cotton gauze or cotton batting, which is capable of absorbing more than a conventional sponge composition and does not leave lint behind in the oral cavity (see abstract, col.2, lines 7-10 and 32-34). Additionally, Speaker et al. provides teachings that braided cord was commonly used in dental applications to provide highly sustained localized topical drug delivery and to serve as a drug reservoir (col.1, lines 55-61).

One having ordinary skill in the art would have found it *prima facie* obvious to combine the teachings of Masci et al., Vermeer et al. and Copelan et al. with Julius or Speaker because Julius teaches the benefits of laminating an absorbent material with at least one layer of a woven or non-woven fabric-like material (i.e., cotton gauze or cotton batting) to enhance the absorbent properties of the material and to avoid leaving lint behind in the oral cavity and Speaker teaches the braided cord was amenable for dental applications, particularly for its ability to provide highly sustained localized topical drug delivery and also to serve as a drug reservoir by which to effect the sustained release. Thus, the use of either a layer of laminated woven or non-woven cotton material over the cotton roll of Masci et al. or the use of a braided cotton cord would have naturally commended themselves, and would have been *prima facie* obvious, to the skilled artisan motivated by the desire to enhance the absorbency of the cotton to retain more of the antiseptic and/or to sustain localized topical delivery of the antiseptic over a longer period of time, thereby enhancing the therapeutic effect of the antiseptic agent.

Regarding the specific dimensions of the cotton roll or the pouch, the determination of the optimum diameter or length of the cotton roll or pouch to be employed would have been a matter well within the purview of the skilled artisan. Such a determination would have been made in accordance with a variety of factors, including, but not limited to, the size of the subject's mouth, the medicament impregnated into the cotton roll, the dose of the medicament to be administered, the overall size of the cotton rolls to be packaged and the number of cotton rolls per single packet. Moreover, Applicant is reminded that where the only difference between the prior art and the claimed is a recitation of the

relative dimensions of the claimed composition of matter, and wherein such a difference in the dimensions does not result in an appreciable difference in function of the composition, then the presently claimed dimensions do not patentably distinguish the presently claimed composition from that of the cited prior art. Please see MPEP §2144.04(IV).

Response to Applicant's Arguments

Applicant's remarks have been fully and carefully considered, but fail to be persuasive.

Applicant argues that the rejection set forth under 35 U.S.C. 103(a) is a "bag of parts" rejection, relies upon Applicant's specification, and is unsupported by any factual basis, motivation or evidence. This argument is not persuasive because Applicant has not overcome the rejection as it was set forth in the previous Office Action and again repeated *supra* and the motivation that was provided for each and every modification that was asserted would have been obvious to one of ordinary skill in the art. Applicant's attention is directed to the rejection as it was set forth in the previous Office Action and again above, which will not be repeated in total or in part herein so as not to burden the record.

Applicant states that the PTO has ignored all of the physical elements of the claimed invention. This is not persuasive. Applicant is directed to each and every cited reference, which provides not only a teaching, but also a motivation to use or modify, the reference to Masci et al. to provide all of the physically required elements of the claimed invention.

For clarity of the record, Applicant is reminded that, regarding intended uses of combinations of "matter", i.e., physical components, a recitation of the intended use of such a combination must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Additionally, a prior art composition and the presently claimed invention cannot be show to be patentably distinct if the prior art structure is capable of performing the

intended use as presently claimed. It is clear from the discussion of Masci et al. that the cotton roll would be amenable for use in the same manner as Applicant has intended by the present claims.

A preamble limitation is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). A preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention and the preamble language extols benefits or features of the claimed invention that would necessarily be present in the prior art structure.

Please also see MPEP §2111.02[R-3], which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim)...During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim.:.If a prior art structure is capable

of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)."

Applicant further states that the motivation to combine references must come from the references, "not out of mid air or the desire for better results" (see paragraph bridging pages 17-18). However, Applicant is reminded that an express motivation to combine is not required to be explicitly stated in the prior art in order to construct a finding of obviousness. Please reference MPEP §2145(X), which states; "However, there is no requirement that an express, written motivation to combine must appear in the prior art references before a finding of obviousness." The motivation to combine the references is legitimate and is clearly supported by the fact that improved results would have motivated the skilled artisan to combine the references to enhance the therapeutic benefit or effect. This is not motivation "out of midair", but rather a realistic motivation to improve upon what was already known, and generally available to, the skilled artisan at the time of the invention.

Applicant submits that the *prima facie* case of obviousness must rest on proven facts, not opinion or conjecture of the Examiner and that it is "procedurally impossible for an Applicant to rebut a non-properly proven *prima facie* case where there is no evidence." (see page 18 of Applicant's remarks) This is not the present case. The *prima facie* case of obviousness has been supported not only by references, but also scientific reasoning and motivation. Nowhere in the Office Action does the rejection take the position that it is the opinion or conjecture of the Examiner. Accordingly, the burden is shifted to Applicant to demonstrate patentable distinction of the claimed invention over the prior art in view of the evidence that has already been presented by the Examiner. Please see the rejection set forth under 35 U.S.C. 103(a) described in detail *supra*.

Regarding Applicant's arguments against each reference individually, Applicant is reminded that the rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Applicant clearly does not address the combined teachings as a whole, but rather focuses solely on the discrete

teachings of each of the cited references and asserts that, since neither reference teaches the presently claimed invention in its entirety, that the rejection is improper. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, rejections under 35 U.S.C. 103(a) are based upon combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference(s) with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test in what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see also *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Lastly, Applicant appears to be arguing that the number of references cited in the rejection under 35 U.S.C. 103(a) is somehow indicative of non-obviousness. In response to Applicant's argument that the Examiner, in Applicant's opinion, has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. Please reference *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

For these reasons, and those set forth in the rejection above under 35 U.S.C. 103(a), rejection of claims 1-4 and 6-15 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-4 and 6-15 remains proper and is **maintained**.

Claim 5 remains **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

The requirement for restriction has been reconsidered, but finality is maintained.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Leslie A. Royds
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October 20, 2006

10/22/06
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SUPERVISORY PATENT EXAMINER